

MAR 11 2004

K040453

510(k) Summary

General Information

Classification	Class III
Trade Name	AutoPulse™ Resuscitation System Model 100
Submitter	Revivant Corporation 775 Palomar Avenue Sunnyvale, CA 94085 408-524-3500
Contact	Bob H. Katz Vice President, Operations

Intended Use

The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.

Predicate Devices

K851139	Thumper™ Model 1005
K011046	AutoPulse™ Resuscitation System Model 100
K022345	AutoPulse™ Resuscitation System Model 100
K032852	AutoPulse™ Resuscitation System Model 100

Device Description

AutoPulse Resuscitation System Model 100 ("Device") is an automated, portable, battery powered device that compresses the chest of an adult human as an adjunct to manual CPR. The Device consists of a single use chest compression assembly (CCA) that includes a patient liner, and a reusable platform that contains a user control panel, a drive mechanism, a control system, and a power system (rechargeable battery).

Materials

All materials used in the manufacture of the AutoPulse Resuscitation System Model 100 are suitable for this use and have been used in numerous previously cleared products.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The AutoPulse Resuscitation System Model 100 is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.



MAR 11 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Revivant Corporation
c/o Mr. Bob H. Katz
Vice President and Chief Operating Officer
775 Palomar Avenue
Sunnyvale, CA 94085

Re: K040453
AutoPulse™ Resuscitation System Model 100
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III (three)
Product Code: DRM
Dated: February 20, 2004
Received: February 27, 2004

Dear Mr. Katz:

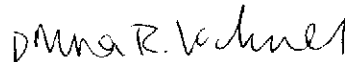
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040453

Device Name: AutoPulse™ Resuscitation System Model 100

Indications For Use: The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Kachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040453

Page 1 of ____